REMARKS

Prior to entry of the present amendment, claims 1-57 are pending in the application. Claims 1-54, due to a restriction requirement, are withdrawn from consideration. Claim 56 is rejected under 35 U.S.C. §112, second paragraph, claim 57 is rejected under 35 U.S.C. §112, first paragraph, and claims 55 and 57 are rejected under 35 U.S.C. §103. Applicants address each of these rejections as follows.

Claim Amendments

Claim 55 has been amended to require the test compound to specifically bind to a polypeptide containing the sequence of SEQ ID NO:6, or a fragment containing amino acids 469-518 of SEQ ID NO:6 or amino acids 739-748 of SEQ ID NO:6. Support for this amendment is found, for example, at page 13, lines 7-12, and page 55, line 28, to page 56, line 1 of the specification as filed. Claim 56 has been amended to delete the phrase "and does not comprise the full-length sequence of SEQ ID NO:6." New claim 58 has been added. Support for claim 58 is found, for example, at page 8, lines 3-4, of the specification. Withdrawn claims 1-54 have been cancelled.

No new matter has been added by the present amendment. Applicants reserve the right to pursue any cancelled subject matter in this or in a continuing application.

Priority

The Office states (page 3):

> [T]here are no certified copies for foreign priority documents DE 101 36 009.6 and DE 102 10 425.5 and no translations for priority documents PCT/DE02/02699, DE 101 36 009.6 and DE 102 10 425.5 ...claims 55-57 are hereby assigned the priority date of January 26, 2004, the filing date of the instant application.

Applicants, herewith, enclose an English language translation of PCT/DE02/02699. In addition, Applicants note that they have requested certified copies of DE 101 36 009.6 and DE 102 10 425.5 and will submit such copies and their translation as soon as possible with a supplemental reply.

Rejection under 35 U.S.C. §112, second paragraph

Claim 56 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite. In particular, the Office states (page 3):

> It is not clear if the fragment comprising amino acids 469-518 and 739-748 consists of a fragment with the two amino acid sequences directly adjacent to each other or separated by other amino acids. Further it is not clear if the fragment comprising amino acids 469-518 and 739-748 consists of a contiguous peptide fragment of SEQ ID NO:6.

Applicants respectfully traverse this basis for rejection.

Claim 56 is directed to a protein fragment that contains amino acids 469-518 and 739-748 of SEQ ID NO:6. Applicants submit that the meaning of the claim language is clear. Namely, the present claim encompasses fragments which contain the two amino

acid sequences (amino acids 469-518 and 739-748 of SEQ ID NO:6), irrespective of their orientation and/or placement within the protein fragment.

On this point, Applicants also note that new claim 58, which depends from claim 56, has been added. 37 C.F.R. §1.75(c) states:

> One or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application. (emphasis added)

Claim 58 is directed to a contiguous sequence of SEQ ID NO:6, where the sequence includes amino acids 469-518 and amino acids 739-748 of SEQ ID NO:6. Claim 58, as a dependent claim, further limits the scope of claim 56 and also clarifies that claim 56 is not limited to contiguous sequences of SEQ ID NO:6 containing amino acids 469-518 and 739-748 of SEQ ID NO:6. Applicants respectfully submit that the rejection under 35 U.S.C. §112, second paragraph, may be withdrawn.

Rejection under 35 U.S.C. §112, first paragraph

Claim 57 is rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. The Office asserts that, with regard to the adenocarcinoma cell line recited in Claim 57, "there is no information in the specification about the deposit of adenocarcinoma cell line 23132 or whether the cell line is readily available to the public." Applicants respectfully submit that the Office's assertion is in error.

As an initial matter, Applicants note that the specification as filed, for

example, at page 8, lines 14-15, and page 10, line 9, recites DSM ACC 201 as the DSMZ ("Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH") Accession Number for adenocarcinoma cell line 23132. Moreover, the translation of priority application PCT/DE02/02699 submitted herewith, at page 3, lines 9-12, states that adenocarcinoma cell line 23132 is deposited under number ACC 201 at the DSMZ.

M.P.E.P. §2402 states:

> To facilitate the recognition of deposited biological material in patent applications throughout the world, the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure was established in 1977, and became operational in 1981. The Treaty requires signatory countries, like the United States, to recognize a deposit with any depository which has been approved by the World Intellectual Property Organization (WIPO). (Emphasis added.)

The DSMZ is listed as an International Depository Authority approved by WIPO in M.P.E.P. § 2405. Applicants also note that adenocarcinoma cell line 23132 is currently publicly available from the DSMZ as evidenced by the printout from the DSMZ provided as Exhibit A. Moreover, Applicants note that the 23132 cell line was deposited with the DSMZ under DSM ACC 201 at least as early as the December 22, 1999 filing date of WO 00/37489 ("the '489 publication"). In support of this assertion, Applicants direct the Office's attention to Exhibit B which includes the cover page of the '489 publication indicating a filing date of December 22, 1999 and page 4, lines 25-26, of the '489 publication where DSMZ Accession Number DSM ACC 201 is provided for

adenocarcinoma cell line 23132. The December 22, 1999 filing date of the '489 publication precedes the July 24, 2001 priority date of the present application.

In view of the above, Applicants submit that claim 57 is enabled by the specification as filed because the specification recites the accession number of adenocarcinoma cell line 23132 and the cell line was deposited with the DSMZ before the July 24, 2001 priority date of the present application. The 35 U.S.C. §112, first paragraph rejection of Claim 57 should be withdrawn.

Rejection under 35 U.S.C. §103(a)

Claims 55 and 57 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hensel et al. (Cancer Res. 59:5299-5306, 1999; hereafter "Hensel") in view of Vollmers et al. (Cancer 76:550-557, 1995; hereafter "Vollmers"). The Office states (pages 6 and 7):

> Hensel et al disclose a test compound, antibody SC-1, that binds to the adenocarcinoma cell line 23132 and induces apoptosis of that cell line (see Figure 5). Hensel et al does not specifically teach that antibody SC-1 does not induce apoptosis of control cells. Vollmers et al, teaches that the antibody SC-1, does not induce apoptosis in normal tissues (p551, 1st column, 2nd paragraph). (Emphasis original.)

Claim 55, as amended, is directed to a method requiring the steps of contacting a cell expressing the amino acid sequence of SEQ ID NO:6, or a fragment thereof containing amino acids 469-518 of SEQ ID NO:6 or amino acids 739-748 of SEQ ID NO:6, with a test compound, where the compound specifically binds to the polypeptide

containing the sequence of SEQ ID NO:6, or the fragment containing amino acids 469-518 of SEQ ID NO:6 or amino acids 739-748 of SEQ ID NO:6, and determining whether the test compound induces apoptosis of the cell and not of a control cell contacted with the test compound. Hensel and Vollmers teach an antibody, SC-1, which binds to proteins expressed by the 23132 cell line. As detailed below, Applicants submit that neither Hensel nor Vollmers, alone or in combination, teaches a compound which specifically binds to a polypeptide containing the sequence of SEQ ID NO:6, or a fragment thereof.

As taught in Applicants' specification, for instance in Example 2 at pages 53 and 54, SEQ ID NO:6 is the amino acid sequence of a novel isoform of CFR-1 that has an approximate molecular weight of 130 kD determined using polyacrylamide gel electrophoresis (see also Figure 1A of the present application). In contrast, Vollmers and Hensel describe an antibody that binds a 49 kD and a 82 kD protein expressed by the 23132 cell line, respectively. (Both Vollmers and Hensel also use polyacrylamide gel electrophoresis to determine the molecular weight.) Clearly, a 130 kD protein is not the same as a 49 or 82 kD protein. Accordingly, Applicants submit that Hensel and Vollmers, alone or in combination, fail to teach or suggest a candidate compound that specifically binds to a polypeptide containing the sequence of SEQ ID NO:6, or a fragment thereof, much less that it would be desirable to identify candidate therapeutic compounds

that bind a polypeptide containing the sequence of SEQ ID NO:6 or a fragment thereof containing amino acids 469-518 of SEQ ID NO:6 or amino acids 739-748 of SEQ ID NO:6. As the cited art, even in combination, fails to teach or suggest every element of the claim 55 as amended, it cannot render claim 55 and its dependent claims obvious. The 35 U.S.C. § 103 rejection should be withdrawn.

CONCLUSION

Applicants submit that the application is now in condition for allowance, and such action is hereby respectfully requested.

Enclosed is a Petition to extend the period for replying to the Office Action for three (3) months, to and including December 20, 2006, and a check in payment of the required extension fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 20 December 2006

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